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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/275,605	08/17/1999	JAY M. SHORT	DIVER 1140-2	5334

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HALE AND DORR LLP
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NEW YORK, NY 10022

EXAMINER

NASHED, NASHAAT T

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/375,605

Applicant(s)
Short, J. M.

Examiner
Nashaat T. Nashed

Art Unit
1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 23, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 73-93 is/are pending in the application.
- 4a) Of the above, claim(s) 79-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 73-78 and 82-93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

The application has been amended as requested in the communication filed May 23, 2003. Accordingly, claims 1-72 have been canceled, and claims 73-93 have been entered.

Claims 73-78 and 82-93 are either generic or drawn to the elected species, i. e., polyketide synthase. They are under consideration in this Office action. Claims 79-81 are directed to non-elected species, and therefore are not considered until a generic claim is considered allowable.

The terminal disclaimers filed on May 23, 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any one of U. S. Patents 5,958,672; and 5,938,250 as well as any patent matured from any of copending U. S. patent applications serial numbers 09/714,780 have been reviewed and are accepted. The terminal disclaimers have been recorded.

Applicant is advised that should claim 92 be found allowable, claim 93 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 73-78 and 82-93 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for the rejections:

- (a) Claim 73 contains two confusing steps which render the claim indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The claim is drawn to a method of obtaining a mutant protein having a desired activity. Step (b) is drawn to mutagenizing at least one member of the library. It is not clear whether the applicant intends to claim a method in which the entire library is subjected to mutagenesis, or prior to the mutagenesis step a selection step in which one or more nucleic acid encoding for a desired activity are selected and either subjecting them individually or collecting them in one container and

- subjecting them to mutagenesis to generate a mutagenized library. Step (c) is also confusing because it is not clear whether the entire mutagenized library would be expressed or only the desired members.
- (e) claims 74-78 and 82-93 are included in this rejection because they are dependent on rejected claims and do not correct the deficiencies of the claim from which they depend.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 73-78 and 82-93 are rejected under 35 U.S.C. § 102(e) as being anticipated by Thompson *et al.* (U. S. P. 5,824,485) for the reasons set forth in the prior Office action, paper numbers 7, 12, and 20.

Claims 73-78 and 82-93 are rejected under 35 U.S.C. § 103 as being unpatentable over Thompson *et al.* in view of the state of the art as exemplified by the cited art, Stemmer *et al.* (Stemmer *et al.* Proc. Natl. Acad. Sci. U. S. A. 1994, 91, 10747-10751) and Arnold *et al.* for the reasons set forth in the prior Office action, paper numbers 7, 12, and 20.

In response to the above rejections, applicant argue that the priority document of the Thompson *et al.* patent have not enabled the instant claims and therefore, Thompson *et al.* is not a prior art against his application, presumably, because applicant claim priority to provisional application 60/008,316.

Applicants' arguments filed 5/19/03 have been fully considered but they are not deemed to be persuasive. Assuming that the instant claims are not enabled in the priority document of the Thompson *et al.* patent, the Thompson *et al.* patent remains a prior art against the instant application because provisional application 60/008,316, filed 12/7/95 fails to enable and describe the instant claims. Consequently, the priority date for the instant claims is the filing date of the parent application serial number 08/651,568 (568) filed 5/22/96. The Thompson *et al.* patent is matured from serial number 08/639,255 (255), filed 4/24/96. Thus, the 255 patent application of Thompson *et al.* has an earlier filing date than that of 568 patent application which the instant application is a continuing application. New claims 73-78 and 82-93 are drawn to the same subject matter of previously rejected and now canceled claims 41-50 and 56-72.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Serial Number: 09/375,605
Art Unit: 1652

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday, and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone numbers for this Group are (703) 305-3014 and (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Nashaat T. Nashed, Ph. D.
Primary Examiner